

Amendments to the Claims

Please amend Claims 1, 13, 24, 33-65, 70 and 75 to read as follows. Note that all the claims currently pending in this application, including those not presently being amended, have been reproduced below.

1. (Currently Amended) A method of sterilizing and/or sanitizing a container, said method comprising the steps of:

See orig
2

generating a sterilant vapor, the sterilant being maintained in a completely vapor state;

positioning a nozzle through an opening in the container and to a position no closer than 15 mm from any internal surface of the container that is perpendicular to a principal direction of flow of sterilant vapor from the nozzle;

A' discharging the generated sterilant vapor through the nozzle and into the container; and

purging the container of the discharged sterilant.

2. (Original) A method according to Claim 1, wherein after said positioning step, the nozzle is positioned no closer than 15 mm from the bottom of the container.

3. (Original) A method according to Claim 1, wherein the container comprises a shoulder below the opening and in said positioning step the nozzle is positioned just below the shoulder.

4. (Original) A method according to Claim 1, wherein after said positioning step, the nozzle is inserted within 1/6 and 5/6 the height of the container.

5. (Original) A method according to Claim 1, wherein the sterilant
comprises hydrogen peroxide.

6. (Original) A method according to Claim 1, further comprising the step of heating the nozzle.

7. (Original) A method according to Claim 1, wherein the container is formed at least in part of PET.

A!
8. (Original) A method according to Claim 1, wherein said purging step comprises forcing heated gas into the container through the nozzle.

9. (Original) A method according to Claim 1, wherein the nozzle has a diameter no greater than one-half the diameter of the opening of the container.

10. (Original) A method according to Claim 1, wherein the sterilant vapor used in said discharging step and a gas used in said purging step are at temperatures no greater than 160° F.

11. (Original) A method according to Claim 1, wherein said purging step is effected no longer than 30 seconds from said discharging step.

12. (Original) A method according to Claim 1, further comprising the step of positioning the nozzle above the opening of the container and discharging the sterilant vapor onto the exterior of the container.

13. (Currently Amended) A method of sterilizing and/or sanitizing a container, the container having an opening of a predetermined diameter, a ratio of the interior surface area of the container to the cross-sectional area of the opening being at least 7.5, said method comprising the steps of:

generating a sterilant vapor, the sterilant being maintained in a completely vapor state;

positioning a nozzle through the opening in the container, the nozzle having a diameter no greater than one-half the predetermined diameter of the opening of the container;

discharging the generated sterilant vapor through the nozzle and into the container; and

purging the container of the discharged sterilant.

14. (Original) A method according to Claim 13, wherein the sterilant comprises hydrogen peroxide.

15. (Original) A method according to Claim 13, further comprising the step of heating the nozzle.

16. (Original) A method according to Claim 13, wherein the container is formed at least in part of PET.

17. (Original) A method according to Claim 13, wherein said purging step comprises forcing heated gas into the container through the nozzle.

18. (Original) A method according to Claim 13, wherein after said positioning step, the nozzle is disposed no closer than 15 mm from any internal surface of the container that is perpendicular to the direction of flow from the nozzle.

A

19. (Original) A method according to Claim 13, wherein after said positioning step the nozzle is inserted within 1/6 and 5/6 the height of the container.

20. (Original) A method according to Claim 13, wherein the sterilant vapor used in said discharging step and a gas used in said purging step are at temperatures no greater than 160° F.

21. (Original) A method according to Claim 13, wherein said purging step is effected no longer than 30 seconds from said discharging step.

22. (Original) A method according to Claim 13, further comprising the step of positioning the nozzle above the opening of the container and discharging the sterilant vapor onto the exterior of the container.

23. (Original) A method according to Claim 13, wherein the predetermined diameter of the opening of the container is no more than one-half the maximum diameter of the container.

24. (Currently Amended) A method of sterilizing and/or sanitizing a PET container, said method comprising the steps of:

generating a sterilant vapor having a temperature no greater than 160° F,
the sterilant being maintained in a completely vapor state;
A' position a nozzle through an opening in the container;
 discharging the generated sterilant vapor through the nozzle and into the container; and
 purging the container of the discharged sterilant with a heated gas having a temperature no greater than 160° F, wherein said purging step is completed no longer than 30 seconds from a beginning of said discharging step.

25. (Original) A method according to Claim 24, wherein the sterilant comprises hydrogen peroxide.

26. (Original) A method according to Claim 24, further comprising the step of heating the nozzle.

27. (Original) A method according to Claim 24, wherein the container is formed in part of PET.

28. (Original) A method according to Claim 24, wherein in said purging step, the heated gas is discharged into the container through the nozzle.

29. (Original) A method according to Claim 24, wherein in said positioning step, the nozzle is disposed no closer than 15 mm from any internal surface of the container that is perpendicular to the direction of flow from the nozzle.

A'

30. (Original) A method according to Claim 24, wherein after said positioning step the nozzle is inserted within 1/6 and 5/6 the height of the container.

31. (Original) A method according to Claim 24, wherein the opening of the container has a predetermined diameter, a ratio of the interior surface area of the container to the cross-sectional area of the opening is at least 7.5, and the nozzle has a diameter no greater than one-half the predetermined diameter of the opening of the container.

32. (Original) A method according to Claim 24, further comprising the step of positioning the nozzle above the opening of the container and discharging the sterilant vapor onto the exterior of the container.

33. (Currently Amended) ~~An~~ In combination, a container and an apparatus for sterilizing and/or sanitizing ~~a~~ the container, said apparatus comprising:
a generator of sterilant vapor, the sterilant being maintained in a completely vapor state;

a nozzle communicating with said generator;
a positioning mechanism for positioning said nozzle through an opening in the container and to a position no closer than 15 mm from any internal surface of the container that is perpendicular to the direction of flow of sterilant vapor from the nozzle;
and

A
a controller for controlling discharging of the generated sterilant vapor through said nozzle and into the container and purging of the container of the discharged sterilant.

34. (Currently Amended) ~~An~~ apparatus A combination according to Claim 33, wherein said positioning mechanism positions the nozzle no closer than 15 mm from the bottom of the container.

35. (Currently Amended) ~~An apparatus~~ A combination according to Claim 33, wherein the container comprises a shoulder below the opening and said positioning mechanism positions said nozzle just below the shoulder.

36. (Currently Amended) ~~An apparatus~~ A combination according to Claim 33, wherein said positioning mechanism inserts the nozzle within 1/6 and 5/6 the height of the container.

37. (Currently Amended) ~~An apparatus~~ A combination according to Claim 33, wherein the sterilant comprises hydrogen peroxide.

A¹
38. (Currently Amended) ~~An apparatus~~ A combination according to Claim 33, further comprising a heater for heating said nozzle.

39. (Currently Amended) ~~An apparatus~~ A combination according to Claim 33, wherein the container is formed at least in part of PET.

40. (Currently Amended) ~~An apparatus~~ A combination according to Claim 33, wherein in purging, said controller controls forcing of heated gas into the container through said nozzle.

41. (Currently Amended) ~~An apparatus~~ A combination according to Claim 33, wherein the opening of the container has a predetermined diameter, a ratio of the

interior surface area of the container to the cross-sectional area of the opening is at least 7.5, and said nozzle has a diameter no greater than one-half the diameter of the opening of the container.

42. (Currently Amended) ~~An apparatus A combination~~ according to Claim 33, wherein said controller controls the sterilant vapor and a purge gas to be at temperatures no greater than 160° F.

43. (Currently Amended) ~~An apparatus A combination~~ according to Claim 33, wherein said controller controls purging to be effected no longer than 30 seconds from discharging of the sterilant.

A¹

44. (Currently Amended) ~~An apparatus A combination~~ according to Claim 33, wherein said controller further controls positioning of the nozzle above the opening of the container and discharging of the sterilant vapor onto the exterior of the container.

45. (Currently Amended) ~~An In combination, a container and an~~ apparatus for sterilizing and/or sanitizing ~~a~~ the container, the container having an opening of a predetermined diameter, a ~~the~~ ratio of the interior surface area of the container to the cross-sectional area of the opening being at least 7.5, said apparatus comprising:

a generator of sterilant vapor, ~~the sterilant being maintained in a completely vapor state;~~

a nozzle communicating with said generator, said nozzle having a diameter no greater than one-half the predetermined diameter of the opening of the container;

a positioning mechanism for positioning said nozzle through the opening in the container; and

a controller for controlling discharging of the generated sterilant vapor through said nozzle and into the container and purging of the container of the discharged sterilant.

46. (Currently Amended) An apparatus A combination according to Claim 45, wherein the sterilant comprises hydrogen peroxide.

A' 47. (Currently Amended) An apparatus A combination according to Claim 45, further comprising a heater for heating said nozzle.

48. (Currently Amended) An apparatus A combination according to Claim 45, wherein the container is formed at least in part of PET.

49. (Currently Amended) An apparatus A combination according to Claim 45, wherein in purging, said controller controls forcing of heated gas into the container through said nozzle.

50. (Currently Amended) An apparatus A combination according to Claim 45, wherein said positioning mechanism positions said nozzle no closer than 15 mm

from any internal surface of the container that is perpendicular to the direction of flow from the nozzle.

51. (Currently Amended) ~~An apparatus A combination~~ according to Claim 45, wherein said positioning mechanism inserts the nozzle within 1/6 and 5/6 of the height of the container.

52. (Currently Amended) ~~An apparatus A combination~~ according to Claim 45, wherein said controller controls the sterilant vapor and a flush gas to be at temperatures no greater than 160° F.

53. (Currently Amended) ~~An apparatus A combination~~ according to Claim 45, wherein said controller controls purging to be effected no longer than 30 seconds from discharging of the sterilant.

54. (Currently Amended) ~~An apparatus A combination~~ according to Claim 45, wherein said controller further controls positioning of the nozzle above the opening of the container and discharging of the sterilant vapor onto the exterior of the container.

55. (Currently Amended) ~~An apparatus A combination~~ according to Claim 45, wherein the predetermined diameter of the opening of the container is no more than one-half the maximum diameter of the container.

56. (Currently Amended) ~~An~~ In combination, a PET container and an
apparatus for sterilizing and/or sanitizing ~~a~~ the PET container, said apparatus comprising:
 a generator of sterilant vapor having a temperature no greater than 160° F,
the sterilant being maintained in a completely vapor state;
 a nozzle communicating with said generator;
 a positioning mechanism for positioning said nozzle through an opening in
the container; and
 a controller for controlling discharging of the generated sterilant vapor
through said nozzle and into the container and purging of the container of the discharged
sterilant with a heated gas having a temperature no greater than 160° F, wherein said
controller controls purging to be completed no longer than 30 seconds from discharging of
the sterilant.

A' 57. (Currently Amended) ~~An~~ apparatus A combination according to
Claim 56, wherein the sterilant comprises hydrogen peroxide.

58. (Currently Amended) ~~An~~ apparatus A combination according to
Claim 56, further comprising a heater for heating said nozzle.

59. (Currently Amended) ~~An~~ apparatus A combination according to
Claim 56, wherein the container is formed at least in part of PET.

60. (Currently Amended) ~~An apparatus~~ A combination according to Claim 56, wherein in purging, said controller controls forcing of the heated gas into the container through said nozzle.

61. (Currently Amended) ~~An apparatus~~ A combination according to Claim 56, wherein said positioning mechanism positions said nozzle to a position no closer than 15 mm from any internal surface of the container that is perpendicular to a principle direction of flow of sterilant vapor from the nozzle.

62. (Currently Amended) ~~An apparatus~~ A combination according to Claim 56, wherein said positioning mechanism inserts the nozzle within 1/6 and 5/6 the height of the container.
A¹

63. (Currently Amended) ~~An apparatus~~ A combination according to Claim 56, wherein the opening of the container has a predetermined diameter, a ratio of the interior surface area of the container to the cross-sectional area of the opening is at least 7.5, and said nozzle has a diameter no greater than one-half the diameter of the opening of the container.

64. (Currently Amended) ~~An apparatus~~ A combination according to Claim 56, wherein said controller further controls positioning of the nozzle above the opening of the container and discharging of the sterilant vapor onto the exterior of the container.

65. (Currently Amended) A method of sterilizing and/or sanitizing a container having a volume b (l), said method comprising the steps of:

generating hydrogen peroxide sterilant vapor having a temperature T₁ (°F),

the sterilant being maintained in a completely vapor state;

discharging a mass a (mg) of the generated sterilant vapor into the container; and

purging the container of the discharged sterilant with heated gas having a volume c (l) and a temperature T₂ (°F), wherein said generating, discharging and purging steps are controlled so as to effect a reduction of Bacillus spores in the container by a predetermined amount X (log) is effected by satisfying the following equation

A1

$$X = (0.138 \times a/b) + (0.066 \times T_1) - (0.00083 \times c/b) + (0.021 \times T_2) + (0.008347 \times d) - 11.357,$$

wherein a is the mass of discharged sterilant vapor (mg),

b is the container volume (l),

c is the volume of purging gas (l),

d is the ambient relative humidity (%RH), (%RH),

T₁ is the temperature of the discharged sterilant vapor (°F), and

T₂ is the temperature of the purging gas (°F).

66. (Original) A method according to Claim 65, wherein the spores are Bacillus subtilis var. globigii.

67. (Original) A method according to Claim 65, wherein the predetermined reduction amount (X) of the spores in the container equals at least 6 log.

68. (Original) A method according to Claim 65, wherein the residual sterilant is reduced in said purging step to a desired level (Z) (mg/l) by satisfying the following equation:

$$Z = (0.030 \times a/b) - (0.043 \times T_1) - (0.040 \times c/b) - (0.075 \times T_2) + 15.747.$$

69. (Original) A method according to Claim 65, wherein the sterilant comprises 35% hydrogen peroxide.

A¹
70. (Currently Amended) A method of sterilizing and/or sanitizing a container having a volume b (l), said method comprising the steps of:

generating a hydrogen peroxide sterilant vapor having a temperature T₁ (°F), the sterilant being maintained in a completely vapor state;

discharging a mass a (mg) of the generated sterilant vapor into the container; and

purging the container of the discharged sterilant with heated gas having a volume c (l) and a temperature T₂ (°F), wherein said generating, discharging and purging steps are controlled so as to effect a reduction of yeast ascospores in the container by a predetermined amount Y (log) is effected by satisfying the following equation

$$Y = (0.063 \times a/b) + (0.023 \times T_1) - (0.00036 \times c/b) + (0.052 \times T_2) + (0.009 \times d) - 3.611,$$

wherein ~~a~~ is the mass of discharged sterilant vapor (mg);

~~b~~ is the container volume (l);

~~c~~ is the volume of purging gas (l);

~~d~~ is the ambient relative humidity (%RH); (%RH).

~~T₁~~ is the temperature of the discharged sterilant vapor (°F), and

~~T₂~~ is the temperature of the purging gas (°F).

71. (Original) A method according to Claim 70, wherein the ascospores are of the yeast Saccharomyces cerevisiae.

A |

72. (Original) A method according to Claim 70, wherein the predetermined reduction amount (Y) of the ascospores in the container equals at least 5 log.

73. (Original) A method according to Claim 70, wherein the residual sterilant is reduced in said purging step to a desired level (mg/l) (Z) by satisfying the following equation:

$$Z = (0.030 \times a/b) - (0.043 \times T_1) - (0.040 \times c/b) - (0.075 \times T_2) + 15.74.$$

74. (Original) A method according to Claim 70, wherein the sterilant comprises 35% hydrogen peroxide.

75. (Currently Amended) A method of sterilizing and/or sanitizing a non-heat-set PET container having a volume b (l), said method comprising the steps of:
generating hydrogen peroxide sterilant vapor having a temperature T₁ (°F),
the sterilant being maintained in a completely vapor state;
discharging a mass a (mg) of the generated sterilant vapor into the container; and
purging the container of the discharged sterilant with heated gas having a volume c (l) and a temperature T₂ (°F), wherein said generating, discharging and purging steps are controlled so as to effect a reduction of the sterilant in the container to a predetermined amount Z (mg/l) at 24 hours after said purging step is effected by satisfying the following equation

$$Z = (0.030 \times a/b) - (0.043 \times T_1) - (0.040 \times c/b) - (0.075 \times T_2) + 15.747,$$

15.747.

wherein a is the mass of discharged sterilant vapor (mg);
b is the container volume (l);
c is the volume of purging gas (l);
T₁ is the temperature of the discharged sterilant vapor (°F), and
T₂ is the temperature of the purging gas (°F).

76. (Original) A method according to Claim 75, wherein the sterilant comprises 35% hydrogen peroxide.

77. (Original) A method according to Claim 75, wherein the predetermined amount is 0.5 mg/l at 24 hours after said purging step.

A'
